USGI Medical
Special 510(k) Device Modification
USGI g-Cath Tissue Anchor Delivery Catheter

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

OCT 2 0 2010

a. Company Name:	USGI Medical
b. Company Address:	1140 Calle Cordillera San Clemente, CA 92673
c. Telephone: Fax:	(949) 369-3890 (949) 369-3891
d. Contact Person:	Mary Lou Mooney Vice President of Clinical, Regulatory & Quality
e. Date Summary Prepared:	October 21, 2010

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	g-Cath Tissue Anchor Delivery Catheter
b. Common Name:	Non-absorbable surgical suture
c. Classification Name:	Non-absorbable (PET surgical suture, 878.5000

3. IDENTIFICATION OF PREDICATE DEVICES

g-Cath Tissue Anchor Delivery Catheter	USGI Medical (K061276, K100251)

4. DESCRIPTION OF THE DEVICE

The g-Cath Tissue Anchor Delivery Catheter is a sterile, single patient use device that contains a nitinol/polyester/titanium tissue anchor pair within the catheter lumen. The anchor pair is deployed through the catheter lumen to compress and approximate tissue.

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5. STATEMENT OF INTENDED USE

The g-Cath Tissue Anchor Deliver Catheter is intended for approximation of soft tissue in minimally invasive gastroenterology procedures, e.g. fistula closure, perforation/leak closure and repair of dilated gastric tissue.

6. COMPARISON WITH PREDICATE DEVICES

The g-Cath Tissue Anchor Delivery Catheter is comparable to the predicate devices in terms of intended use, technology, and materials.

Bench testing was conducted to ensure that the modified device performs as intended when used according to its instructions for use.

7. SUMMARY OF PERFORMANCE DATA

Design control activities for the device modifications were completed in accordance with 21CFR 820.30 and USGI Medical documented design control procedures. Human factors considerations were also incorporated into the device modifications. Risk analysis was performed in accordance with USGI Medical procedures and ISO 14971 to identify any risks associated with the modifications. Bench testing confirmed that the device met its performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

USGI Medical
% Ms. Mary Lou Mooney
VP, Clinical, Regulatory & Quality
1140 Calle Cordillera
San Clemente, California 92673

OCT 20 2010

Re: K102916
Trade/Device Name: g-Cath Tissue Anchor Delivery Catheter
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT, GDW, HET
Dated: September 30, 2010
Received: October 1, 2010

Dear Ms. Mooney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 2 0 2010

510(k) Number (if known): K102916

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510(k) Number (if known):

The g-Cath Tissue Anchor Delivery Catheter is intended for approximation of soft tissue in minimally invasive gastroenterology procedures, e.g., fistula closure, perforation/leak closure and repair of dilated gastric tissue.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102916